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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,693	01/29/2002	Andrew Shiau	UCAL-256/01US	9894

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MORGAN, LEWIS & BOCKIUS, LLP.
3300 HILLVIEW AVENUE
PALO ALTO, CA 94304

EXAMINER	
MORAN, MARJORIE A	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Office Action Summary	Application No.	Applicant(s)	
	09/830,693	SHIAU ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-141* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-141* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-24, 72-133, and 140-141, drawn to methods of identifying compounds which modulates nuclear receptor activity or modulates binding of a ligand to a nuclear receptor, classified in class 703, subclass 2. This Group is subject to election of species, as set forth below.

II. Claims 29-33, drawn to a method of modulating nuclear receptor activity in a mammal, classified in class 424, subclass 198.1. This Group is subject to election of species, as set forth below.

III. Claims 34-35 and 39, drawn to a machine readable storage medium capable of graphical three-dimensional representation, classified in class 702, subclass 27.

IV. Claims 40-43, drawn to a machine readable storage medium comprising a program for correspondence of data, classified in class 708, subclass 403. This Group is also subject to an election of species, as set forth below.

V. Claims 44-48, drawn to a crystal comprising a portion of an estrogen receptor and an agonist, classified in class 350, subclass 399.

VI. Claims 49-51, drawn to a crystal comprising a portion of an estrogen receptor and an antagonist, classified in class 350, subclass 399.

VII. Claims 52-66, drawn to a computational method of designing a nuclear receptor ligand, classified in class 703, subclass 12. This Group is also subject to election of species, as set forth below.

VIII. Claims 67-71, drawn to a method of modulating nuclear receptor activity in a mammal by administering a chemically modified ligand, classified in class 424, subclass 198.1. This Group is subject to election of species, as set forth below.

IX. Claims 134-135, drawn to method of modulating nuclear receptor activity in a mammal by administering an antagonist, classified in class 424, subclass 198.1.

X. Claims 136-139, drawn to an isolated protein complex, classified in class 350, subclass 399.

The inventions are distinct, each from the other because of the following reasons:

Invention I is not related to any of Inventions II and VIII-IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods with different intended results, which recite different method steps. The compound administered in the method of Group II is not limited to be the same as that identified in the method of Group I, nor is the method of Group I limited to be one for identifying a compound for administration in the method of Group II. Further, the steps of any of the methods may be performed without knowledge of or reference to the steps or results of any other method. For these reasons, the method of Group I has a different operation, functions and effect than any of Groups II and VIII-IX.

Invention I is not related to either of Inventions III or IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of Group I does not recite use of the machine readable storage media, or instructions stored thereon of either of Groups III or IV. The instructions stored on the machine readable storage media of Groups II and IV are not those for running the method of Group I; i.e. the program steps do not reflect the method steps recited in the claims of Group I, therefore the products of Groups III and IV are not those for use in the method of Group I. Further, the products of Groups III and IV may be used in variety of methods, such as comparison of different configurations of the receptor, comparison of different receptor/protein structures, etc.

Invention I is not related to any of Inventions V-VI or X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of Group I does not recite use or production of the crystals or protein complex of Groups V-VI and X. Further, the products of Groups V-VI and X are not limited to be those produced by or used in the method of Group I.

Invention I is not related to Invention VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Groups I and VII are directed to different

results and recite different method steps and use of different products. Specifically, the method of Group VII recites modification of a ligand, no ligand or modification step is recited in the method of Group I. As the methods have different modes of operation, different functions, and different effects, the Groups are unrelated.

None of Inventions II and VIII-IX is related to either of Groups III-IV. A machine readable storage medium is not capable of administration to a mammal, thus the product of Groups III-IV are not capable of being used in any of the methods of administration of Groups II and VIII-IX.

None of Inventions II and VIII-IX is related to any of Inventions V-VI and X. The proteins of Groups V-VI and X are not limited to be those administered in the methods of Group II, VIII or IX, and none of Groups II, VIII, of IX recite use of the compounds of Groups V-VI and X. Thus, the Groups are unrelated.

Neither of Groups II or IX is related to Group VII. The method of Group VII is not limited to design or produce the compounds administered in the methods of Groups II of IX, and neither of Groups II or IX recite administration of the compound designed in the method of Group VII, thus the Groups are unrelated.

Groups VII and VIII are separate and distinct. While the compound administered in the method of Group VIII may be designed by a method similar to that of Group VII, the Groups are directed to different methods reciting different method steps and different intended results. Further, the compound administered in the method of Group VIII is not limited to be that designed by the method of Group VII, nor is the compound

designed in the method of Group VII limited to be one for administration in the method of Group VIII. For these reasons, the Groups are separate and distinct.

Inventions II and VIII-IX are not related. While the method of each Group recites a similar preamble and a step of administration, each Group recites use of a different compound, and thus would be expected to produce a different result. Further, the steps of any one Group may be performed without knowledge of or reference to the steps or results of any other Group. Thus, the Groups recite different functions, and different effects, and are unrelated.

Neither of Inventions III and IV is related to any of Inventions V-VI and X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the media of Groups III and IV are not capable of use or production of the crystals or protein of Groups V-VI and X. Further, the instructions on the media of Groups III and IV are not directed to design, make or use the crystals or protein of Groups V-VI and X. For these reasons, the Groups are not related.

Neither of Inventions III or IV is related to Invention VII. The computer readable media of Groups III and IV is not limited to run the method of Group VII, nor to comprise instructions similar to the method of Group VII. The method of Group VII is not limited to be one run by instruction on the medium of either of Groups III or IV. Thus, Group VII is not related to either of Inventions III or IV.

Inventions III and IV are unrelated. The product of each Group is directed to comprise a different set of instructions which would produce different results. As the products of each Group, by virtue of the instructions thereon, has different modes of operation, different functions, and different effects, the Groups are unrelated.

Groups V, VI, and X are separate and distinct. The product of each Group is limited to be a different structure from the product of any other Group. Although a portion of each structure is similar, the claims of each Groups are specifically directed to comprise different elements within the entirety of the claimed structure. As the structures are different, they would be expected to have different biochemical properties and to behave differently is methods of use. As each Group is directed to a separate and distinct product, the Groups are not related.

Invention VII is not related to any of Inventions V-VI or X. None of the products of Groups V-VI and X is limited to be one made by, designed by, or used in the method of Group VII. Similarly, the method of Group VII does not recite design, production, or use of any of the products of Groups V-VI or X. As the products of Groups V-VI and X are not capable of use in the method of Group VII, they are not related to Group VII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Further, these inventions are distinct for the reasons given above and the search required for any one Group is not required for any other Group, therefore restriction for examination purposes as indicated is proper.

This application contains claims directed to patentably distinct species of the claimed invention, as set forth below.

If **Group I** is elected, then applicant is further required to elect from each of the following species:

(A) a test compound which is an agonist, or is an antagonist;

(B) a single nuclear receptor; e.g. from those recited in claims 11 and 16;

If **Group II or Group IV** is elected, then applicant is further required to elect a single nuclear receptor; e.g. from those recited in claims 31 and 41.

If **Group VII** is elected, then applicant is further required to elect from each of the following species:

(A) a chemical modification which enhances a an interaction (e.g. claim 55), or which reduces an interaction (e.g. claim 56);

(B) a single nuclear receptor; e.g. from those recited in claim 57;

(C) a single ligand (see e.g. claims 61, 64, 66).

If Group **VIII** is elected, then applicant must further elect a ligand which is an agonist or antagonist .

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 40 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
6/24/04

mam